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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,519	09/27/2000	Bruce W. Gibbs	BC-0256-P02	2122

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GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,519

Applicant(s)

GIBBS, BRUCE W.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/22/00.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The examiner would like to point out that she was not refusing to consider the IDS filed 12/22/00, but did not have, at the time of the last office action, any of the Foreign Patents or Published Applications and Other Documents listed references in her possession at that time. The noted box containing the cited references was never delivered to the examiner at the time of the last office action. However, the Foreign Patents or Published Applications and Other Documents listed in the IDS filed 12/22/00 have been located and scanned into the electronic file. Therefore, at this time, they have been considered. See attached initialed PTO-1449.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Keller et al. (6,200,287). Keller discloses an apheresis system and method wherein the system includes a disposable preconnected cassette assembly as well as a number of tubing assemblies (20/50/60/80/90/100) interconnected thereto. Tubing assembly (20/60) is a blood inlet/return and blood component return assembly. A

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blood processing vessel (352), i.e. centrifuge, is interconnected to the tubing assemblies and cassette. A red blood cell collection assembly is connected to the cassette for receiving separated red blood cells and comprises a collection bag (950). Keller further teaches that selective filtering may be desired to remove white blood cells. For example, leukoreduction may be desired to reduce any likelihood of febrile non-hemolytic transfusion reactions. If such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag. A plasma collection bag (94) and a platelet collection bag (84) are connected to the cassette assembly via tubing. During use, blood is removed from a patient or donor, separated into components, including RBC, platelets, and plasma, using a centrifuge vessel using the pre-connected disposable system and red blood cell collection assembly. The components, including RBC, plasma and platelets, are stored in their respective containers. Keller also teaches that the RBC may pass through a leukocyte filter before being finally stored. Keller also discloses that the RBC collection tubing assembly further includes a sterile barrier filter/drip spike assembly (956). Also, a storage solution may be added that advantageously facilitate storage of the RBCs for a longer period of time than without storage solution. The solution may be contained in a separate storage solution bag that can be selectively interconnected to the RBC collection bag. Such selective interconnection may be provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly. The use of assembly

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facilitates the maintenance of a closed system, thereby effectively avoiding bacterial contamination. Since Keller discloses that the leukocyte filter is used to provide leukoreduction and that the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag, it is implicit that the system will have a filter connected to a RBC storage reservoir or bag. This filtration is inherently done after centrifugation. Further, since a storage solution would be added to the final RBC storage bag or reservoir, and is taught to be connected to the bag via the barrier/spike and storage solution, it would inherently be placed between the centrifuge and leukoreduction filter to achieve the desired leukocyte free product. See figures 1, 2A & 2B as well as the entire disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287). Keller et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the air removal bag is interconnected to the RBC storage bag. Keller does disclose the use of an air removal tubing segment (100) including an air removal bag (104) that is connected to the

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cassette assembly for receiving air from the cassette assembly and the centrifuge during priming. It would have been obvious at the time of the invention to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claims 3, 4 & 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287) in view of Minshall et al. (5,009,654). Keller et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically the use of frangible connectors in the tubing between the leukoreduction filter and RBC collection bag. Keller does teach of selective interconnection being provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly.

Minshall discloses a tubing assembly that is a closed apheresis kit or circuit containing tubing and bags connected. It is also taught that the tubing may include normally closed frangible connectors in the flow path of each portion to keep the circuit sterile. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the tubing of Keller to include frangible connectors in the tubing between the filter and collection bag to keep the pathway sterile, since Keller suggests the use of an assembly that is a closed system to effectively avoiding bacterial contamination.

Response to Arguments

Applicant's arguments filed March 18th, 2003 have been fully considered but they are not persuasive. Applicant argues that Keller does not disclose that the leukoreduction filter is interconnected between the RBC collection bag and the RBC storage bag as claimed in claims 1 and 7. The examiner respectfully disagrees. Keller teaches that a leukocyte reduction filter may be connected to the red cell storage bag (i.e. collection bag), the red blood cells can be transferred via gravity through the filter and the filtered red cells then passed into a second, storage bag. See column 55, lines 20-39.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

pmb
July 23rd, 2004


PATRICIA BIANCO
PRIMARY EXAMINER

Tricia Bianco
Patent Examiner
Art Unit 3762